

Applicant: William Galbraith

Application No.: 10/804,592

Amendment to Final Office Action dated October 18, 2007

Docket No.: P-6007/1 (102-585 RCE)

Page 2 of 7

REMARKS

Reconsideration of this application is respectfully requested.

At the forefront, Applicant would like to note that, in the Final Office Action, the Examiner stated that Applicant's arguments are moot in view of the new grounds of rejection, and that "the previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) of the claims have been withdrawn." (Page 6). The Examiner then stated that new grounds of rejection are made in view of Applicant's amendment "requiring the attachment of a ligand to the insoluble support via an epoxy linkage." (Pages 6-7). However, it is respectfully noted that Applicant did not make this amendment in its most recent amendments, and further that the rejections of the instant Final Office Action are the exact same as those in the previous Office Action (dated May 15, 2007). Rather, Applicant amended claims 1 and 24 to state "said ligand being bindable to albumin." This limitation, added by the last response, is not at all addressed in the present Final Office Action. It is respectfully submitted that there are no "new ground(s) of rejection" in the present Final Office Action.

To facilitate further prosecution of this application, Applicant sets forth the following arguments.

Claims 1-6, 24-31 and 52-53 are in the application. Applicant has not amended any claims of the application.

In the Final Office Action, the Examiner rejected claims 1, 2, 4, 6, 24-27, 52 and 53 under 35 U.S.C. §103(a) as being allegedly unpatentable over Sjoholm et al. (U.S. Patent No. 4,061,466) in view of Spring et al. (U.S. Patent No. 5,643,721) and further in view of Degen et al. (U.S. Patent No. 5,567,615). The Examiner admitted that "Sjoholm et al. fail to teach the ligand attached to the support via an epoxy linkage." The Examiner relied on Spring et al. and Degen et al. for allegedly overcoming this deficiency.

Applicant: William Galbraith

Application No.: 10/804,592

Amendment to Final Office Action dated October 18, 2007

Docket No.: P-6007/1 (102-585 RCE)

Page 3 of 7

Sjoholm et al. is directed to a biologically active composition and the use thereof. As indicated at col. 2, ll. 35-38, “[t]he biologically active substance is composed of macromolecules such as proteins, polysaccharides, polyamino acids, nucleic acids, separately or in mixtures with each other.” The Examiner specifically relied on Example 9 of Sjoholm et al. Example 9 of Sjoholm et al. specifically refers back to Example 1, stating that micro particles were prepared “in a manner similar to example 1.” (Col. 9, ll. 37-39). In Example 1, albumin is immobilized on a support surface. In the method set forth in Example 1, micro particles are prepared by mixing the binding and support materials with albumin, thus resulting in micro particles “with the immobilized albumin.” Since Example 9 incorporates the method of Example 1, the bromosulphophthalein of Example 9 is exposed to (and mixed with) albumin, which is directly contrary to claims 1 and 24.

It is clear that Sjoholm et al. intended Example 9 to include albumin in the formation of the micro particles, since examples which exclude albumin specifically so state. With reference to Example 4, it is specifically stated that “the albumin changed for Concanavalin A (2 mg/ml).” In addition, in Example 10, it is stated that “poly-L-lysine could be entrapped in micro particles instead of albumin.” Thus, it is clear that where Sjoholm et al. intended on having albumin substituted for a second material, it is explicitly stated so. In addition, as indicated above, Sjoholm et al. discloses the use of mixtures of proteins and polysaccharides. (See, col. 2, ll. 35-38). Also, column 2, lines 38-40 indicates that the biologically active substance (which may be a combination of materials) may be conjugated with a colourant (Example 9 discloses bromosulphophthalein as a dye).

In contrast to Sjoholm et al., claims 1 and 24 of the subject application require attaching a ligand consisting of bromosulphophthalein as claimed without being exposed to albumin. There is no such disclosure or suggestion in Sjoholm et al. Moreover, Spring et al. and Degen et al. fail to overcome this deficiency. It is respectfully submitted that claims 1 and 24, along with

Applicant: William Galbraith

Application No.: 10/804,592

Amendment to Final Office Action dated October 18, 2007

Docket No.: P-6007/1 (102-585 RCE)

Page 4 of 7

dependent claims 2, 4, 6, 25-27, 52 and 53, are patentable over Sjoholm et al., Spring et al. and Degen et al., each taken alone or in combination.

Further, it is respectfully submitted that the combination of Sjoholm et al., Degen et al. and Spring et al. as suggested by the Examiner is improper. Spring et al. disclose a medium incorporating bioreagents immobilized to a solid phase, which are then dispersed within a latex binding reagent. (See col. 9, ll. 25-60). Spring et al. specifically states that the use of a latex binding reagent "enables the bioreagent/solid phase complexes to irreversibly adhere to the surface of a support material when dried thereon." (Col. 9, ll. 32-34). Spring et al. desires the application of the medium to a support material, such as by "brushing, pumping, liquid metering, screen printing, spraying, jetting or dipping the support material into the immobilization medium." (Col. 9, ll. 45-49).

In contrast, Degen et al. disclose an affinity separation method comprising free affinity particles and a target-containing fluid, incorporated into a dynamic filtration apparatus. In fact, Degen et al. states that the affinity particles should be at least 2 times, and more preferably 5-10 times, the pore size of the filtration medium, to "prevent[] any of the affinity particles from passing therethrough." (Col. 7, ll. 15-26). The affinity particles of Degen et al. are thus intended to be free-standing and not encompassed in a latex binding reagent, particularly one that "irreversibly adheres" to the support surface as that disclosed by Spring et al.

Thus, one practicing the filtration method of Degen et al. would not be directed to use the methods described by Spring et al. Spring et al.'s latex binding reagent would completely inhibit the freedom of the affinity particles used by Degen et al.. As such, Spring et al. and Degen et al. are not combinable, and the combination of Degen et al. and Spring et al. as suggested by the Examiner is improper. It is respectfully stated that claims 1 and 24, along with dependent claims 2, 4, 6, 25-27, 52 and 53, are patentable over Sjoholm et al., Spring et al. and Degen et al., each taken alone or in combination.

Applicant: William Galbraith

Application No.: 10/804,592

Amendment to Final Office Action dated October 18, 2007

Docket No.: P-6007/1 (102-585 RCE)

Page 5 of 7

The Examiner rejected claims 1-6, 24-27, 52 and 53 under 35 U.S.C. §103(a) as being allegedly unpatentable over Grahnén et al. (Eur. J. Biochem., 80, 573-580 (1997)) in view of Spring et al. and further in view of Degen et al. The Examiner admitted that “Grahnén et al. fail to teach the ligand attached to the support via an epoxy linkage” and relied on Spring et al. and Degen et al. for allegedly overcoming this deficiency.

Grahnén et al. is directed to a method of preparation of ligandin with glutathione-S-transferase activity from porcine liver cytosol. As set forth at p. 574 of Grahnén et al., bromosulfophthalein is initially prepared with sodium borohydride. Sodium borohydride is a known reducing agent. In particular, the boron of the sodium borohydride complexes with oxygen found on cross-linked sepharose (cross-linked with 2,3-dibromopropanol) as disclosed in Sjoholm et al. With oxygen being complexed in this process, it is unclear how an epoxy linkage can be substituted in. Chemistry is highly unpredictable, particularly the behavior of molecules and their reactions are highly unpredictable. Thus, there is no basis for determining that the hypothetical combination suggested by the Examiner can be achieved. Further, as explained above, the combination of Spring et al. and Degen et al., as suggested by the Examiner, is improper. It is respectfully submitted that claims 1-6, 24-27, 52 and 53 are patentable over Grahnén et al., Spring et al. and Degen et al., each taken alone or in combination.

The Examiner rejected claims 24 and 27-31 under 35 U.S.C. §103(a) as being allegedly unpatentable over Pieper et al. (U.S. Published Patent Application No. 2002/0127739) in view of Grahnén et al., and further in view of Spring et al. and further in view of Degen et al. The Examiner admitted that Pieper et al. fail to teach a ligand of bromosulfophthalein. The Examiner relied on Grahnén et al. for allegedly overcoming this deficiency. The Examiner further relied on Spring et al. and Degen et al. for the alleged notion of substituting an epoxy linkage.

Applicant: William Galbraith

Application No.: 10/804,592

Amendment to Final Office Action dated October 18, 2007

Docket No.: P-6007/1 (102-585 RCE)

Page 6 of 7

Pieper et al. is directed to a method for sample preparation which, as admitted by the Examiner, does not disclose the use of bromosulfophthalein. As set forth at p. 9, paras. [0100]-[0103], the use of antibodies is disclosed for binding to albumin. Claim 24 indicates the use of a ligand with "said ligand being bindable to albumin" and the ligand "consisting of bromosulfophthalein or a salt of bromosulfophthalein or ester of bromosulfophthalein". There is no suggestion or disclosure in Pieper et al. of using a ligand consisting of bromosulfophthalein, as set forth in claim 24, which is bindable to albumin. Moreover, Grahnen et al. does not disclose the use of bromosulfophthalein with albumin. Rather, Grahnen et al. is directed to a method for extracting ligandin, which is an enzyme from pig liver. One skilled in the art would not look to Grahnen et al. to modify Pieper et al. to include a ligand consisting of bromosulfophthalein which is bindable to albumin. Spring et al. and Degen et al. fail to overcome this deficiency.

Further, claims 24 and 27-31 require an epoxy linkage. Pieper et al. has no disclosure or suggestion of using an epoxy linkage with bromosulfophthalein. In fact, Pieper et al. discloses that the binding agent is affixed to the surface of the matrix via a protein. (See paragraph 44). Pieper et al. states that the antibody is affixed via the "use of protein A and/or protein G and/or protein L or the like." (Paragraph 45). Even further, Pieper et al. states that "other methods to immobilize antibodies onto the solid phase may be used [sic] but are generally less preferred because of difficulties controlling the binding reaction or because they result in more antibody becoming inactive resulting in lower binding capacity." (Paragraph 46, emphasis added). One practicing the methods of Pieper et al. would not be led to using an epoxy linker. In fact, as stated above, Pieper et al. specifically teaches away from any methods other than via a protein linker.

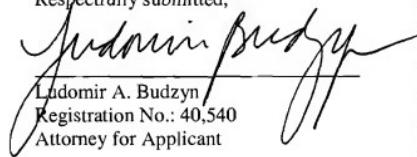
Finally, as stated above the combination of Spring et al. and Degen et al., as suggested by the Examiner, is improper.

Applicant: William Galbraith
Application No.: 10/804,592
Amendment to Final Office Action dated October 18, 2007
Docket No.: P-6007/1 (102-585 RCE)
Page 7 of 7

For the reasons set forth above, it is respectfully submitted that claims 24 and 27-31 are patentable over Pieper et al., Grahenen et al., Spring et al. and Degen et al., each taken alone or in combination.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicant's attorney at the number listed below.

Respectfully submitted,


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